Netech Corporation
% Mukesh Kumar
CEO
Brij Strategic Consultations, LLC
20271 Goldenrod Lane, Suite 2020
Germantown, Maryland 20876

Re: K190437
Trade/Device Name: Delta 3300
Regulation Number: 21 CFR 870.5325
Regulation Name: Defibrillator Tester
Regulatory Class: Class II
Product Code: DRL
Dated: July 29, 2019
Received: July 30, 2019

Dear Mukesh Kumar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole Goodsell
Acting Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190437

Device Name
Delta 3300

Indications for Use *(Describe)*

Netech Corporation Delta 3300 Defibrillator/Pacemaker Analyzer is used to determine that defibrillators and transcutaneous pacemakers are performing within their performance specifications through the measurement of energy output.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 5 – 510(k) Summary

1. 510(k) Submitter:

Netech Corp.
110 Toledo St.
Farmingdale, NY 11735
Phone: 631-531-0100
Email: md@netech.org

2. Company Contact: Mohan Das, President

3. Date of 510 (k) Summary Preparation: August 27, 2019

4. 510(k) Preparer:

Mohan Das, Ph.D
Netech Corp.
110 Toledo St. Farmingdale, NY 11735
Phone: 631-531-0100
Email: md@netech.org

5. Device Classification:

Trade name:	Delta 3300
Common name:	Defibrillator/Pacemaker Analyzer
Device:	Tester, Defibrillator
Regulation:	870.5325
Class:	2
Product Code:	DRL

6. Predicate:

Applicant:	BC Group International, Inc (St Charles, MO)
Device:	DA-2006
510(k) Number:	K110192

7. Device Description… Netech Corporation Delta 3300 Defibrillator/Pacemaker Analyzer is used to determine that defibrillators and transcutaneous pacemakers are performing within their performance specifications through the measurement of energy output.

   The portable battery-powered device is intended for use by trained service technicians. Delta 3300 is a waveform analyzer that determines the characteristics of an electrical discharge signal produced by a defibrillator and transcutaneous pacemaker.

   It provides a basis for verifying the energy output of a defibrillator, including energy, peak current, and peak voltage. The device incorporates a simulation function of ECG and arrhythmia waveforms for verifying the performance of defibrillator monitors.

   Delta 3300 also verifies transcutaneous pacemaker parameters such as pulse rate, width, amplitude, and energy as well as refractory and sensitivity measurement.

8. Indications For Use… Netech Corporation Delta 3300 Defibrillator/Pacemaker Analyzer is used to determine that defibrillators and transcutaneous pacemakers are performing within their performance specifications through the measurement of energy output.
9. Comparison To Predicate… As shown in Table 5, Delta 3300 and the predicate share the same:

- Indications for use
- Classification and product code
- Description – Defibrillator tester
- Technology – Precision testing instrument
- Intended User – Trained service technician

Table 5 – Comparison Table

Characteristics	Device	Predicate	Comparison
510k Number	Applied For	K160761	NA
Common Name	Defibrillator tester	Defibrillator tester	Same
Trade Name	Delta 3300 (Netech Corp)	DA-2006 (BC Group)	NA
Regulation Number	21 CFR 870.5325	21 CFR 870.5325	Same
Product Code	DRL	DRL	Same
Indications For Use	Precision instrument for ensuring that defibrillators and defibrillators with transcutaneous pacemakers comply with performance specifications.	Used to determine that defibrillators and transcutaneous pacemakers are performing within their performance specifications.	Same
Physical Characteristics			
Maximum Voltage	5000V	5000V	Same
Maximum Continuous Power	10W, 10 defib pulses at 360J every 5 min	12W, 10 defib pulses at 360J every 5 min	Power dissipation factor increased by 2 W.
Inductance	<3 uh @ 50 Ohm	<10 uh	Lower inductance factor by 7uh.
Tech Spec: Sampling Time	20 us	100 us	80 us faster sampling rate.
Tech Spec: Sampling Window	60 ms	100 ms	40 ms sampling window for improved resolution

Tech Spec: Display Resolution	Auto Ranging 0.01 < 9.9J 0.1 > 10, < 99.9 1 > 100	0.1 J (Low Range) 1 J (High Range)	0.01 resolution <9.9J 0.1 resolution >10 -99.9 J
Elec Spec: Load Settings	50 Ω, +/- 1%	50 Ω, +/- 1%	Same
Elec Spec: Accuracy (50) Ω	Auto Ranging +/- 1% of reading for < 99.99 Joules +/- 2% for >100 Joules	+/- 2% of reading +/- 2 Joules	+/- 1% of reading for <99J +/- 2% for >100 Joules
Physical: Dimensions	260mm X 160mm X 640mm	248.9mm X 205.7mm X 120.7mm	Smaller foot print
Weight	1.5 Kg	2.37 Kg	Lighter
Operating Temp	15 to 40 °C	15 to 40 °C	Same
Storage Temp	-20 to +60 °C	-20 to +60 °C	Same

10. Performance Testing… Delta 3300 passed the following non-clinical bench tests: (Animal /Clinical testing was not performed).

    - Electrical Safety – IEC 61010-1:2010 (Third Edition)… Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
    - EMC – EN 61000-3-2… Electromagnetic Compatibility (EMC) Part 3-2 Limits – Limits for harmonic current emissions
    - EMC – EN 61000-3-3… Electromagnetic Compatibility (EMC) Part 3 Limits – Section 3: Limitation of voltage fluctuations and flicker in public low voltage supply systems. For harmonic current emissions.
    - IEC 61508 - Embedded software verification and validation.

11. Substantial Equivalence… Delta 3300 successfully followed the pathway to Substantial Equivalence in the FDA guidance document, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications" (July 2014). The steps are summarized below:

    - The predicate is legally marketed because it was found substantially equivalent through the 510(k) process.
    - The subject and predicate devices have the same intended use (and indications).
    - Technological differences between the subject and primary predicate were evaluated. It was found that the technological differences doesn't introduce any new and/or different concerns relating to its safety or effectiveness.
    - The following methods for evaluation of the effects of different characteristics on safety and effectiveness were deemed acceptable—electrical safety, electromagnetic compatibility, and non-clinical performance testing.
    - Data from these tests demonstrated equivalence and support the indications for use.

In summary, all necessary testing has been performed and the results support the conclusion that Delta 3300 is substantially equivalent to the legally marketed predicate, DA-2006, based on intended use, materials, technology, and design, and the device thus does not raise any concerns of safety or effectiveness. This finding of substantial equivalence warrants clearance of Delta 3300 for marketing activities.